REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of one month of the period for response to the Office Action. Authorization to charge the prescribed fee to our deposit account is enclosed.

The withdrawal of the indicated allowability of claims 3 to 4, 11 to 16, 20 to 24, 26 to 28, 32 to 34, 36 to 43, 49 and 51 to 53 upon further consideration of the prior art is noted. The prior art rejection applied to these claims is discussed below.

The Examiner rejected claims 36 under 35 USC 112, second paragraph, as being indefinite and for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to step (i) of that claim to which the Examiner specifically referred, the step (now labeled (j)) has been amended to remove redundant language and to simply refer to the recovered protein micellar mass having a protein content of at least 100 wt% (N x 6.25).

Having regard thereto, it is submitted that all claims comply with 35 USC 112, second paragraph, and that the rejection of claim 36 thereunder should be withdrawn.

The Examiner rejected claims 3 to 4, 11 to 16, 24, 26 to 28, 32 to 34, 36 to 43, 49 and 51 to 53 under 35 USC 103(a) as being obvious over Murray (USP 6,005,076) in view of Rossi et al. Reconsideration is requested having regard to the amended form of the claims and the remarks herein.

The claims of the application have been limited to the production of canola protein isolate in order to simplify the issues for consideration. In addition, it has been clarified in the claims that, following crushing of the oil seed to form canola oil and canola oil seed meal, the canola oil is separated from the canola oil seed meal.

This application is directed to a process of preparing canola protein isolates by a plurality of steps starting with canola oil seeds. The canola oil seeds are crushed to form canola oil and canola oil seed meal therefrom. Following separation of the canola oil from the canola oil seed meal, the canola oil seed meal is solvent extracted to recover residual canola oil therefrom and then the solvent is removed from the extracted oil seed meal at a temperature of from 15° to 50°C under vacuum to provide a desolventized canola oil seed meal. It is this desolventized canola oil seed meal which is processed to recover the canola protein isolate.

The recovery of the canola protein isolate is effected by extracting the desolventized canola oil seed meal to cause solubilization of canola protein in the desolventized canola oil seed meal and to form an aqueous canola protein solution having a pH of about 5 to about 6.8. The aqueous canola protein solution is separated from residual canola oil seed meal, following which the aqueous canola protein solution is concentrated while maintaining the ionic strength substantially constant by using a selective membrane technique to provide a concentrated canola protein solution. The concentrated canola protein solution then is diluted into chilled water having a temperature of below 15°C to cause the formation of discrete canola protein particles in the aqueous phase in the form of micelles. The canola protein micelles are settled to form an amorphous, sticky, gelatinous, gluten-like protein micellar mass, which is recovered from supernatant, the protein micellar mass having a canola protein content of at least 90 wt% (N x 6.25) on a dry weight basis. The various independent claims define various modifications to this procedure, as set forth below.

As set forth in the disclosure (para 0003), it is common practice in the recovery of canola oil from canola oil seeds to crush the canola oil seeds to remove most of the canola oil and to hot solvent extract the residual meal to recover the remainder of the canola oil. The residual meal from the solvent extraction contains residual solvent, which is recovered from the meal for reuse before the canola oil seed meal is disposed of by the crusher. In the solvent recovery operation, the

canola oil seed meal is heated to temperatures of about 120° to 140°C in a procedure called "toasting".

The present invention is based on the surprising discovery that the amount of canola protein which can be extracted from canola oil seed meal can be significantly increased if the solvent recovery is effected on ambient temperature desolventized canola oil seed meal. The ability to extract more canola protein from the meal improves the overall economics of the process. In addition, a product of improved quality is obtained. It is submitted that the Murray et al reference does not describe or suggest the process defined in the rejected claims.

It is conceded that the Murray et al reference describes steps (e) to (j) of the independent claims, with the exception of claim 36, which recites that the canola protein isolate contains at least about 100 wt% protein (N x 6.25) and with the exception of the "wherein" clauses in each step (j). It is submitted that the Murray et al reference does not disclose or suggest the combination of steps with steps (a) to (d) of the independent claims with steps (e) to (j) and the "wherein" clauses recited therein.

The Examiner refers to Example 3 of Murray et al. This Example illustrates the use of cold pressed extraction of canola seeds in the formation of canola protein isolate. The Example indicates that intact canola seeds were fed into a cold extrusion press and crushed. The compacted seed debris, less extruded oil, was ground in a standard mill to a consistency similar to that of commercial canola meal and then processed by the protein extraction and recovery process described in Example 2 to form a canola protein isolate. In that process, a commercial Polish rapeseed meal was processed, first by extracting the meal using an aqueous salt solution, which is the equivalent of step (e) of the independent claims herein, except for claim 24, wherein the extraction is effected using water. As the Examiner states:

> "Murray does not explicitly teach a desolventized oil seed meal under vacuum."

In particular, Murray et al does not disclose or suggest the combination of steps (a) to (d) of the independent claims with steps (e) to (j) of those claims.

The Examiner attempts to remedy the shortcomings of Murray et al by reference to Rossi et al. Rossi et al is concerned with a procedure of obtaining a food grade protein meal from defatted sunflower. As noted above, applicants claims are directed to the formation of a canola protein isolate by the processing of canola oil seeds.

As the Examiner states, Rossi et al effect an initial oil extraction process on sunflower seeds to produce a "cake" that is rich in protein. The protein is said to have good nutritional and functional qualities and to be suitable for various applications in the preparation of food formulations. However, it is indicated that the traditional oil extraction techniques on sunflower seeds do not provide cake suitable for human nutrition, owing to heat damage during processing, particularly during pressing and solvent elimination, and high fibre content.

The aim of Rossi et al was:

> "... to determine whether it is possible, after extraction of the oil by an industrial solvent-process, to obtain from the cake a food-grade meal." (page 309, left-hand col., last complete paragraph).

Applicants procedure are directed to the production of a canola protein isolate. The provision of a canola oil seed meal (or "cake") is but an intermediate step in a multi-step operation.

In the Rossi procedure, as seen in Figure 1, on page 310, sunflower seeds are processed by a multi-step operation, with certain samples being taken and processed at various stages of a conventional sunflower seed processing operation. This sample processing, as the Examiner observes, includes vacuum desolventizing of samples B and C at 40°C, sample B being a partly defatted cake and sample C being a totally defatted cake, the desolventized samples being further subjected to a sieving operation.

Rossi et al provide detailed analysis of the samples and conclude:

> "By replacing the present system's desolventizer-toaster with the desolventizer operating under vacuum, and by adding a mechanical sieving system, it would be possible to produce meals of high protein content and good nutritional value" (page 311, right-hand column, paragraph 2 after the heading "Conclusion").

Thus, to achieve the goal of Rossi et al (i.e. a food-grade meal), it is necessary to not only desolventize the sunflower seed meal under vacuum, but also to effect a sieving operation on the meal. As already noted, the goal of the present invention is different, namely to obtain a canola protein isolate, which does not require any sieving operation to be carried out on the canola oil seed meal.

As discussed above, in the present invention, canola protein isolate is obtained in a higher protein yield than obtained from conventional toasted canola oil seed meal. There is no suggestion in Rossi et al that, in producing a canola protein isolate, increased yields can be obtained by desolventizing canola oil seed meal at a temperature of about 15° to about 50°C under vacuum, as required by applicants claims.

As the Examiner states in the Office Action, with particular reference to claim 3:

> "The instant claims are essentially drawn to a process of preparing a protein isolate comprising processing a desolventized oil seed meal. The desolventized oil seed meal is obtained by the process described in claims 3(a)-3(c). The actual process to recover protein isolate from the desolventized oil seed meal is described in claims 3(d)-3(i)."

Steps 3(a) to 3(c) are now steps 3(a) to 3(d) and steps 3(d) to 3(i) are now steps 3(e) to 3(j). As discussed above, with the noted exceptions, the other independent claims recite similar steps.

Independent claim 3 specifically recites that the process steps 3(a) to 3(j) are effected on a semi-continuous basis while independent claim 4 recites that the steps 4(e) to 4(j) are effected on a continuous basis. Claims 13 to 16 are dependent on claim 4 and recites specific process conditions in effecting the canola

protein extraction step from the desolventized canola oil seed meal on a continuous basis. Claim 32 is dependent on claim 4 and recites the degree of dilution of a concentrated canola protein solution in the micelle formation step. Claims 33 and 34 are dependent on claim 32 and recite specific conditions of the dilution step.

Independent claim 20 specifically requires that, following the separation of the aqueous canola protein solution resulting from the extraction step from the residual canola oil seed meal, the aqueous canola protein solution is subjected to a pigment removal step. Claims 21 to 23 are dependent on claim 20 and recite specific procedures of pigment removal.

Independent claim 24 recites that the desolventized canola oil seed meal is extracted with water and subsequent thereto salt is added to the resulting aqueous canola protein solution to provide an aqueous canola protein solution having an ionic strength of at least 0.10.

Independent claim 26 recites that the aqueous canola protein solution is concentrated by using a selective membrane technique to produce a concentrated protein solution having a canola protein content of at least 250 g/L. Independent claim 27 recites that, following concentration of the aqueous canola protein solution using a selected membrane technique, the concentrated canola protein solution is warmed to a temperature of at least 20°C to decrease the viscosity of the concentrated canola protein solution but not beyond a temperature above which the temperature of the concentrated canola protein solution does not permit micelle formation in the dilution step. Claim 28 is dependent on claim 27 and recites the specific temperature range of 25°to 40°C. Independent claim 36 recites that the canola protein isolate obtained has a canola protein content of at least 100 wt% (N x 6.25) d.b.

Independent claim 37 recites, that, following recovering of the canola protein micellar mass from the supernatant from the deposition of this mass, the supernatant is processed on a batch, semi-continuous or continuous basis, to recover additional quantities of canola protein isolate from the supernatant. Claims 38 to 41 and claims 51 to 53 are dependent, directly or indirectly, on claim 37 and recite specific procedures for processing the supernatant to obtain the additional canola protein isolate.

Independent claim 42 recites that, as an alternative to the diluting, settling and recovering steps effected on the concentrated canola protein solution, the canola protein solution is dialyzed to reduce the salt content thereof and to cause the formation of canola protein micelles and a canola protein isolate is recovered from the dialyzed concentrated canola protein solution having a protein content of at least 100 wt% (N x 6.25) d.b. Claim 43 is dependent on claim 42 and recites the manner of recovery of the canola protein isolate.

Independent claim 49 recites that the concentration step effected on the aqueous canola protein solution is effected by ultrafiltration to produce a concentrated canola protein solution having a protein content of at least 200 g/L.

Each of these independent claims and claims dependent thereon recites features not found in Murray et al nor in the combination of Murray et al with Rossi et al, as explained in more detail below.

In the Office Action, the Examiner asserts that:

> "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray of obtaining a protein isolate by first crushing canola seeds (claim 3a), substituting the oil-extraction process (claim 3b) and desolventizing under vacuum process (claim 3c) of Rossi et al. to obtain a desolventized oil seed meal"

As already noted, the starting point of the Murray et al process is an oil seed meal and, when applied to canola, a canola oil seed meal. As the Examiner indicates, Murray et al in col. 2 to 3, ll 66 to 3, states that:

> "The canola meal may be any canola meal resulting from the removal of canola oil from canola seed with varying levels of non-denatured protein, resulting, for example, from hot hexane extraction or cold extraction methods."

The Rossi et al procedure is directed to sunflower seeds and is specifically concerned with the provision of a sunflower oil seed meal (or "cake") which is a food-grade meal. The Rossi et al reference is silent as to any potential further processing of the meal to form a protein isolate. Therefore, a person skilled in the art, would not be motivated to consider the Rossi et al teaching of the processing of sunflower seeds to obtain a food-grade meal as a alternative procedure to obtaining a canola oil seed meal for the Murray et al process. In addition, a person skilled in the art

would not be motivated by Rossi et al to consider that an improved yield of canola protein isolate would be obtained by desolventizing canola oil seed meal under vacuum at a temperature of 15° to 50°C, as claimed herein.

The Examiner goes on to state in the Office Action:

> "..... and then processing said desolventized oil seed meal to obtain a protein isolate by extracting said desolventized oil seed meal to cause solubilization and to form an aqueous protein solution having a pH of about 5-6.8, maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claims 3-4, 11-16, 24, 32-34, 36-37), increase the protein concentration (claim 3), dilute the concentrated protein solution to induce the formation of protein micelles (claim 3-4, 11-16, 24, 32-34, 36-37), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 3-4) because Murray provides and suggests motivation for a method of preparing a protein isolate from a desolventized oil seed meal and Rossi et al. teach a desolventized oil seed meal under vacuum."

As already stated, the fact that Rossi et al teach the desolventized sunflower oil seed meal is produced under vacuum is irrelevant. As already further stated, the process steps (e) to (j) of the independent claims are generally found in Murray et al, subject to the exceptions noted above.

With respect to claims 11 to 16, which are dependent on claim 4, it is submitted that the specific combination of process conditions recited in claim 11 for extraction of the canola protein from the desolventized canola oil seed meal in a continuous process is not found in Murray et al. With respect to claim 24, Murray et al does not disclose a procedure in which desolventized canola oil seed meal is extracted with water and salt is added to the aqueous canola protein solution produced thereby to remove an ionic strength of at least 0.1. With respect to claim 36, Murray et al does not disclose a procedure in which a canola protein islolate having a protein content of at least 100 wt% (N x 6.25) d.b. is obtained. In the only specific information provided in Murray et al with respect to protein content of a canola protein isolate (see Example 1), the protein content is given as 91 wt%.

With respect to claim 36, there is no disclosure in Murray et al of processing supernatant from the deposition of canola protein micelles to recover additional quantities of canola protein isolate.

In the Office Action, the Examiner further states:

"Murray does not specifically disclose that steps (d) to (i) of claims 3-4 are effected in a semi-continuous or continuous mode of operation.

"However, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the steps of (d) through (i) of the process of making a canola protein isolates as taught by Murray, to have been effected in a continuous mode of operation in order to increase the efficiency and overall production capacity of the system. One of ordinary skill in the art would have been motivated to make the process of Murray run in a continuous or semi-continuous mode in order to achieve the maximum efficiency of the production system, thereby increasing production of said protein isolate and increasing financial returns."

The Examiner is correct that Murray et al do not disclose operation of the steps (e) to (j) on a semi-continuous or continuous basis. In any event, claims 3 and 4 are distinguished from the combination of Murray et al and Rossi et al in view of the defects of Rossi et al referred to above.

The Examiner further states in the Office Action:

"Regarding claims 24, 42-43 (i.e. salt is subsequently added to the resulting aqueous protein solution to provide an aqueous protein solution having an ionic strength of at least 0.10), it should be noted since Murray discloses that extracting canola oil seed meal is effected using an aqueous salt solution having an ionic strength of at least 0.2 and a pH of about 5-6 (col. 3 lines 9-11, lines 40-41), it is believed that salt is added to the water at some point during the extraction process."

In this regard, only claim 24 recites the step of extracting with water and subsequently adding salt to the extracted canola protein isolate. The Examiner's comments with respect to claims 42 to 43 are discussed below.

The Examiner is correct that the Murray et al reference describes extracting oil seed meal with aqueous salt solution having an ionic strength of at least 0.2 and pH of about 5 to 6.8, and indeed in Example 1, specially directed to preparation of a canola protein isolate, the canola oil seed meal is extracted with a 0.5 M solution of sodium chloride made from tap water. However, it is submitted that this teaching does not disclose or suggest the two-step procedure defined in claim 24 for forming the aqueous canola protein isolate which is subjected to the concentration step, in which the canola oil seed meal is first extracted with water to

form an aqueous canola protein solution and then salt is added to the latter solution to an ionic strength of at least 0.1 to form the aqueous canola protein solution for concentration.

With respect to claims 42 to 43, these claims define as an alternative procedure of the diluting, settling and recovering steps ((h) to (j)), the concentrated canola protein solution is dialyzed to reduce the salt content thereof and to cause the formation of canola protein micelles and canola protein isolate is recovered from the dialyzed concentrated canola protein solution. In the Office Action, the Examiner states:

> "In this instance, it would be reasonable for one ordinary skill to know that the addition of salt to an aqueous solution would also require a dialyzing step in order to eliminate the salt from the concentration protein solution (claims 42-43)."

However, it is clear that Murray et al contains no suggestion to modify the procedure for micelle formation therein by dialyzing the concentrated canola protein solution to reduce the salt content and thereby cause the formation of canola protein micelles and recovering the canola protein micelles as the canola protein isolate from the dialyzed concentrated canola protein solution.

As discussed above, claims 26 to 49 require concentration of the aqueous canola protein solution to a protein concentration of at least 250 g/L and at least 200 g/L respectively. With respect to these claims, the Examiner comments in the Office Action that:

> "Regarding claim 26, 49 (i.e. said concentration step is effected by ultrafiltration), as noted above, Murray discloses a process step for increasing the protein concentration using a selective membrane technique. It would be reasonable for one of ordinary skill to know that an ultrafiltration technique is within the scope of a selective membrane technique. The normal desire of scientists to improve upon what is already generally known provides the motivation to determine which specific membrane should be used to produce a protein isolate which will have the highest protein content, i.e. greater than 100 g/L, 200 g/L, etc."

The Examiner is correct that the Murray et al reference discloses concentration of aqueous protein solution by a selective membrane technique including ultrafiltration (see, for example, col. 4 line 39). While Murray et al refer to the concentrated protein

solution as having a protein concentration of about 40 to about 200 g/L (see col. 5, l 49), the Murray reference does not disclose, for canola, concentrating the aqueous canola protein solution to a concentration of at least 200 g/L (claim 48) or at least 250 g/L (claim 26).

In Murray et al, the only teaching specially directed to canola is in Examples 1 to 3, Example 1 discloses an extraction step effected on canola oil seed meal to form an aqueous canola protein solution which is concentrated by ultrafiltration to a concentration of 120 mg/ml (120 g/L). The Examples presumably represent the best conditions known to the inventors of Murray et al for producing canola protein isolate and no higher protein concentration is specified or contemplated. Accordingly, the Murray reference provides no motivation to concentrate the aqueous canola protein solution to a concentration of at least 200 g/L or at least 250 g/L as specified in applicants claims.

With respect to claims 27 and 28, claim 27 recites that the concentrated canola protein has a protein content of at least 200 g/L. As discussed in relation to claims 26 and 49, Murray et al does not disclose or suggest concentration of aqueous canola protein solution to such concentration level.

In relation to claims 38 to 41 and 51 to 53 (it is thought the Examiner intended to refer to claims 33 to 41 and 51 to 53), the Examiner states in the Office Action:

> "Regarding claims 38-41, 51-53 (i.e., recovering additional quantities of protein isolate from the supernatant by concentrating the supernatant to a protein concentration of about 100 to 400 g/L), as noted above, Murray discloses increasing the protein concentration; therefore, it would be reasonable for one of ordinary skill to determine at which protein concentration the supernatant should be at (i.e. greater than 100 g/L, 200 g/L, etc.) in order to recover a protein micellar mass that will yield a protein isolate with the highest protein content."

While it is correct that Murray discloses "increasing the protein concentraton", this teaching is with respect to the aqueous protein solution resulting from extraction of the oil seed meal and not with respect to the supernatant from canola protein micelle formation. This concentration step is effected in Murray prior to formation of the canola protein micelles. The Murray et al reference is entirely silent as to the supernatant from the canola micelle formation and potential

processing thereof and presumably this is discarded. In any event, there is no suggestion that the supernatant may contain additional recoverable quantities of canola protein and that such canola protein can be recovered in the form of an isolate.

Accordingly, claims 37 to 41 and 51 to 53, are patentable over Murray et al.

Having regard to the revisions made to the claims and the above discussion, it is submitted that claims 3 to 4, 11 to 16, 24, 26 to 28, 32 to 34, 36 to 43, 49 and 51 to 53 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being obvious over Murray in view of Rossi et al, should be withdrawn.

The Examiner rejected claims 20 to 23 under 35 USC 103(a) as being unpatentable over Murray in view of Rossi et al and further in view of Cook et al (US 5,254,673).

Claims 20 to 23 relate to the provision of the additional step of subjecting the aqueous canola protein solution to a pigment removal step following separation of the aqueous canola protein solution from the residual canola oil seed meal and prior to the concentration step.

The relevance of the combination of Murray and Rossi et al to the basic combination of steps and the distinctions thereover have been discussed above. It is submitted that the Cook et al reference does not remedy these defects.

The Examiner comments in the Office Action that:

> "Murray discloses that the presence of fat in protein production can lead to discoloration resulting from the co-processing of pigments in the meal with the fat."

Presumably the Examiner is referring to lines 31 to 37 of col. 1 of Murray. The passage does not appear to associate the presence of fat with discoloration but specifically refers to co-processing of pigments in the meal with the fat.

The Examiner relies on Cook for the teaching that:

> "Cook et al. disclose a process for zein protein purification from corn meal. Cook et al. disclose that activated carbon powder can be used to further purify said protein from meal (col. 9 example 2)."

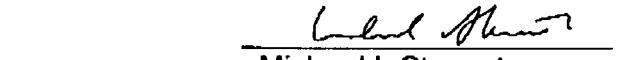
Cook et al describe a purification procedure for the recovering the zein (maize) from corn gluten meal involving a multiple step operation. As the Examiner states, Examples of Cook et al describe the use of powdered activated carbon for purification of the zein.

Cook et al is concerned with zein and not with canola. While Cook et al describe that activated carbon can be incorporated into a protein processing method for pigment removal, it is submitted that this teaching does not disclose or suggest effecting a pigment removal step on the aqueous canola protein solution formed in Murray. In addition, the Cook et al reference does not disclose or suggest a pigment removal step using diafiltration as specifically claimed in claim 21.

Accordingly, it is submitted that claims 20 to 23 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over the Murray in view of Rossi et al and further in view of Cook et al, should be withdrawn.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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